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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,935	01/25/2002	Zairen Sun	16U 107 R1	6950

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ORIGENE TECHNOLOGIES, INCORPORATED
6 TAFT COURT
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ROCKVILLE, MD 20850

EXAMINER
UNGAR, SUSAN NMN

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 03/25/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/054,935	Applicant(s) Sun et al
	Examiner Ungar	Art Unit 1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *one* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 25, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-27* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. Claims 1-27 are pending in the application and are currently under prosecution.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Anthony Caputa, Ph.D., Supervisory Patent Examiner at 703-308-3995. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Group 1. Claims 1-8 are drawn to a polynucleotide encoding SEQ ID NO:2, classified in Class 536, subclass 23.1.

Group 2. Claims 9-13 are drawn to a polypeptide, classified in Class 530, subclass 300+.

Group 3. Claims 14-15 are drawn to a method of treating breast cancer with an agent that regulates a gene classified in Class 514, subclass 44.

Group 4. Claim 14 is drawn to a method of treating breast cancer with an agent that regulates a polypeptide classified in Class 514, subclass 2+.

3. It is noted that, claim 1 is drawn not only to the polynucleotide encoding Urb-ctf but also to SEQ ID NO:2 which appears to be Urb-ctf polypeptide,

therefore, it is assumed for restriction purposes that the Urb-crfs referred to in this claim are both the polynucleotide encoding and the polypeptide encoded.

Group 5. Claims 16 and 17 are drawn to a method of diagnosing human breast cancer by measuring the expression levels of polypeptide, classified in Classes 435, 4, 7.1.

4. It is noted that the claims of the instant application have been determined to include linking claims The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 16. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Groups 6-8. Claims 16 and 17 are drawn to a method of diagnosing human breast cancer by (1) measuring expression level of said gene, (2) determining the genomic structure of said gene, (3) determining the mRNA structure of transcripts from said gene, all of claim 17, each of which is a distinct

invention classified in Classes 435, 4, 6. Applicant is required to elect a single invention for examination. Claim 18 will be examined as it is drawn to the elected invention.

Group 9. Claim 19 is drawn to a method of assessing intervention in a human subject having breast cancer comprising determining the expression levels of human Urb-ctf polypeptide of claim 1 in primary tumor, classified in Class 435, subclasses 4, 7.1.

Group 10. Claim 19 is drawn to a method of assessing intervention in a human subject having breast cancer comprising determining the expression levels of human Urb-ctf polypeptide of claim 1 in cells derived from a tumor, classified in Class 435, subclasses 4, 7.1.

Group 11. Claim 19 is drawn to a method of assessing intervention in a human subject having breast cancer comprising determining the expression levels of human Urb-ctf polynucleotide of claim 1 in primary tumor, classified in Class 435, subclasses 4, 6.

Group 12. Claim 19 is drawn to a method of assessing intervention in a human subject having breast cancer comprising determining the expression levels of human Urb-ctf polynucleotide of claim 1 in cells derived from a tumor, classified in Class 435, subclasses 4, 6.

Group 13. Claim 20, 22 is drawn to a method of identifying an agent that modulates the expression of human Urb-ctf polypeptide of claim classified in Class 435, subclasses 4, 7.1.

Group 14. Claims 20-21 is drawn to a method of identifying an agent that modulates the expression of human Urb-ctf polynucleotide of claim 1, classified in Class 435, subclasses 4, 6.

Group 15. Claims 23-24 are drawn to a non-human transgenic animal, classified in Class 800, subclass 2.

Groups 16-24. Claim 25 is drawn to antibodies which are specific to different epitopes of SEQ ID NO:2, each of which is a distinct invention, classified in Class 530, subclass 350+.

Group 25. Claim 26 is drawn to method of advertising, classified in Class 705, subclass 1.

Group 26. Claim 27 is drawn to method of displaying human Urb-ctf on a computer-readable medium, classified in Class 702, subclass 19.

5. The inventions are distinct, each from the other because of the following reasons:

Inventions 1, 2, 15-24 as disclosed are biologically and chemically distinct, unrelated in structure and function, made by and used in different methods and are therefore distinct inventions.

Inventions 3-14, 25-26 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

The inventions of Groups 1 and 3, 6-8, 11,-12, 14 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be

practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the polynucleotide product as claimed can be used in a materially different process such as producing the encoded polypeptide.

The inventions of Groups 2 and 4-5, 9-10, 13 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the polypeptide product as claimed can be used in a materially different process such as producing the an antibody.

The inventions of Groups 1, 2, 15-24 and 25-26 are not at all related because the inventions of Groups 1,2, 15-24 are not used in any of the methods of Groups 26-27.

The inventions of 15-24 and 3-14 are not at all related because the antibodies of Groups 15-24 are not recited in any of the methods of Groups 3-14.

The inventions of Groups 2 and 4-5, 9,-10, 13 are not at all related because the polypeptides of Group 2 are not used in any of the methods of Groups 4-5, 9-10, 13.

The inventions of Groups 1 and 3, 6-8, 11,-12, 14 are not at all related because the polynucleotides of Group 1 are not used in any of the methods of Goreups 3, 6-8, 11,-12, 14.

The inventions of Groups II and III/VII are not at all related because the antibody of Group II is not used in any of the methods of Groups III and VII.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. Groups 6-8 are further subject to election of a single disclosed species. :2.

Claims 16 is generic to a plurality of disclosed patentably distinct species comprising methods of assaying polynucleotides wherein the methods are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success wherein the methods are the six method disclosed in claim 18.

8. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship

must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

11. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

12. Please note the Notice of Insufficient Filing Fees included with this action. Applicant is required to submit the reqired Fee and return the attached Notice.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
March 24, 2003